Complete Summary

GUIDELINE TITLE

2002 national guideline on the management of trichomonas vaginalis.

BIBLIOGRAPHIC SOURCE(S)

Association for Genitourinary Medicine (AGUM), Medical Society for the Study of Venereal Disease (MSSVD). 2002 national guideline on the management of trichomonas vaginalis. London: Association for Genitourinary Medicine (AGUM), Medical Society for the Study of Venereal Disease (MSSVD); 2002. Various p. [22 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Trichomonas vaginalis infection

GUIDELINE CATEGORY

Diagnosis
Management
Treatment

CLINICAL SPECIALTY

Infectious Diseases
Obstetrics and Gynecology
Urology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To present a national guideline for the management of Trichomonas vaginalis

TARGET POPULATION

Men and women, including pregnant women and women who are breastfeeding, in the United Kingdom with Trichomonas vaginalis infection

Note: Children, specifically babies born to infected mothers and prepubescent girls, with Trichomonas vaginalis infection are considered. However, specific recommendations are not provided.

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

Females:

- Direct observation by a wet smear or acridine orange stained slide from the posterior fornix
- Culture
- Cervical cytology followed by direct observation of vaginal secretions and preferably by culture

Males:

- Direct observation by wet mount or staining
- Urethral culture, culture of first void urine or both
- External genital sampling

Note: Polymerase chain reaction-based diagnostic tests are considered.

Treatment/Management

- Simultaneous treatment of sexual partner(s), and sexual abstinence advice
- Screen for coexistent sexually transmitted infections (STIs)
- Metronidazole
- Follow-up: tests of cure
- Management of treatment failure:
    - Check compliance and exclude vomiting of metronidazole
    - Check possibility of re-infection
    - Check partner(s) has been treated
    - Repeat course of standard treatment
    - High vaginal swab (HVS) or empiric treatment with erythromycin or amoxycillin before re-treating with metronidazole
    - When the organism is one that has evolved with the capability to exist under aerobic conditions anecdotal treatments include:

- Metronidazole with metronidazole per rectum or per vagina (unlicensed)
- High dose oral and intravaginal tinidazole
- High dose intravenous metronidazole
- 6% nonoxynol-9 pessaries
- Acetarsol pessaries
- Paromomycin sulphate pessaries

MAJOR OUTCOMES CONSIDERED

Cure rate

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developers searched Medline for the years 1966-2000 using keywords "Trichomonas vaginalis", "trichomoniasis" limited to "human" and "English". They also searched Medline for the years 1966-2000, using keywords "Trichomonas vaginalis", "trichomoniasis" and "resistance" limited to "human" and "English". In addition, they searched the Cochrane database on treatment of Trichomonas vaginalis in non-pregnant women. They also reviewed the 1998 U.S. Centers for Disease Control and Prevention (CDC) "Guidelines for the Treatment of Sexually Transmitted Diseases", the British National Formulary September 2000, and the Data Sheet Compendium 1999-2000, Rhone-Poulenc Rorer, manufacturers of metronidazole; Dr Herring of the PHLS at Bristol.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence:

Ia

- Evidence obtained from meta-analysis of randomised controlled trials

Ib

- Evidence obtained from at least one randomised controlled trial

IIa

- Evidence obtained from at least one well designed controlled study without randomisation

IIb

- Evidence obtained from at least one other type of well designed quasi-experimental study

III

- Evidence obtained from well designed non-experimental descriptive studies such as comparative studies, correlation studies, and case control studies

IV

- Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The revision process commenced with authors being invited to modify and update their 1999 guidelines. These revised versions were posted on the website for a 3 month period and comments invited. The Clinical Effectiveness Group and the authors concerned considered all suggestions and agreed on any modifications to be made.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grading of Recommendations:

A (Evidence Levels Ia, Ib)

- Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation.

B (Evidence Levels IIa, IIb, III)

- Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation.

C (Evidence Level IV)

- Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities.
- Indicates absence of directly applicable studies of good quality.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The initial versions of the guidelines were sent for review to the following:

- Clinical Effectiveness Group (CEG) members
- Chairs of UK Regional GU Medicine Audit Committees who had responded to an invitation to comment on them
- Chair of the Genitourinary Nurses Association (GUNA)
- President of the Society of Health Advisers in Sexually Transmitted Diseases (SHASTD)
- Clinical Effectiveness Committee of the Faculty of Family Planning and Reproductive Health Care (FFP)

Comments were relayed to the authors and attempts made to reach a consensus on points of contention with ultimate editorial control resting with the Clinical Effectiveness Group. Finally, all the guidelines were ratified by the councils of the two parent societies.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the levels of evidence (I-IV) and grades of recommendation (A-C) are repeated at the end of the "Major Recommendations" field.

Clinical Features

Symptoms

Females (Evidence Level III) (Wolner-Hanseen et al., 1989; Fouts & Kraus, 1980)

- 10% to 50% are asymptomatic.
- The commonest symptoms include vaginal discharge, vulval itching, dysuria, or offensive odor.
- Occasionally the presenting complaint is of low abdominal discomfort.

Males (Evidence Level III) (Kreiger et al., 1993)

- 15% to 50% of men with Trichomonas vaginalis are asymptomatic and usually present as sexual partners of infected women.
- The commonest presentation is with urethral discharge and/or dysuria, indistinguishable from those caused by urethritis of other aetiologies. Other symptoms include urethral irritation and frequency.
- Rarely the patient may complain of a copious purulent urethral discharge, or complications such as prostatitis.

Signs

Females (Evidence Level III) (Wolner-Hanseen et al., 1989; Fouts & Kraus, 1980)

- Vaginal discharge in up to 70%, varying in consistency from thin and scanty to profuse and thick; the classic discharge of frothy yellow occurs in 10% to 30% of women.
- Vulvitis and vaginitis are associated with trichomoniasis.
- Approximately 2% of patients will have strawberry cervix appearance to the naked eye. Higher rates are seen on colposcopic examination.
- 5% to 15% of women will have no abnormalities on examination.

Males (Evidence Level III) (Kreiger et al., 1993)

- Urethral discharge (50% to 60% men), usually small or moderate amounts only.
- No signs, even in the presence of symptoms suggesting urethritis.
- Rarely balanoposthitis.

Complications

There is increasing evidence that Trichomonas vaginalis infection can have a detrimental outcome on pregnancy and is associated with preterm delivery and low birth weight (Evidence Level III) (Saurina & McCormack, 1997; Cotch et al., 1997). There is evidence that trichomonas infection may enhance human immunodeficiency virus (HIV) transmission. (Sorvillo & Kernott, 1998)

Diagnosis

Females (Evidence Level III) (Wolner-Hanssen et al., 1989; Fouts & Kraus, 1980; Bickley et al., 1989; Kreiger et al., 1988; Wiese et al., 2000)

- Direct observation by a wet smear or acridine orange stained slide from the posterior fornix will diagnose 40% to 80% cases.
- Culture media are available and in females up to 95% of cases can be diagnosed by cultures.
- Trichomonads are sometimes reported on cervical cytology, where the sensitivity is approximately 60% to 80%, but there is a false positive rate of about 30%. In such cases it is prudent to confirm the diagnosis by direct observation of vaginal secretions and preferably by culture, if available.

Males (Evidence Level III) (Kreiger et al., 1992)

- Direct observation by wet mount or staining will only diagnose infection in about 30% of cases.
- Urethral culture or culture of first void urine will diagnose 60% to 80% cases, sampling both sites simultaneously will significantly increase the diagnostic rate. External genital sampling will identify a small number of additional cases.

Polymerase chain reaction based diagnostic tests have recently been developed and sensitivities and specificities approaching 100% have been reported. (Madico et al., 1998; Mayta et al., 2000)

Management

General advice

Sexual partner(s) should be treated simultaneously, and sexual abstinence advised until treatment is completed.

Further investigations

Screening for coexistent sexually transmitted infections (STIs) should be undertaken in both men and women.

Treatment (Forna & Gulmezoglu, 2000; Hager et al., 1980; Thin et al., 1979)

The frequency of infection of the urethra and paraurethral glands in females dictates that systemic chemotherapy be given to effect a permanent cure. Most strains of Trichomonas vaginalis are highly susceptible to metronidazole (MTZ) and related drugs (approximately 95% cure rate). There is a spontaneous cure rate in the order of 20% to 25%.

Recommended regimes (Evidence level Ib)

- Metronidazole 2 g orally in a single dose

or

- Metronidazole 400 mg to 500 mg twice daily for 5 to 7 days

The single dose has the advantage of improved compliance and being cheaper; however, there is some evidence to suggest that the failure rate is higher, especially if partners are not treated concurrently.

Patients should be advised not to take alcohol for the duration of treatment and for at least 48 hours afterwards because of the possibility of a disulfiram-like (antabuse effect) reaction.

Allergy (Pearlman et al., 1996; Kurohara et al., 1991)

There is no effective alternative to imidazole compounds. In cases of true allergy, desensitization to metronidazole has been described and could be considered.

Treatment failure

- Check compliance and exclude vomiting of metronidazole
- Check possibility of re-infection
- Check partner(s) has been treated
- Patients who fail to respond to first course of treatment often respond to a repeat course of standard treatment

If this fails and above excluded then (Evidence Level IV or anecdotal):

- Some organisms present in the vagina may interact and reduce effectiveness of metronidazole, so consider a high vaginal swab (HVS) or treat empirically with erythromycin or amoxycillin to reduce beta-haemolytic streptococci before re-treating with metronidazole.
- If above unlikely and there is persistent treatment failure the likelihood is that the organism is one that has evolved with the capability to exist under aerobic conditions. In these situations there is no effective recommended treatment. Sensitivity testing is currently unavailable. Reported successful treatments include:
    - Metronidazole 400 mg three times daily with metronidazole 1 g per rectum or 1 g per vagina (unlicensed) daily for 7 days or longer (some clinicians have added zinc sulphate 1% vaginal douches or vaginal washes with 3% acetic acid to the regimen)
    - High dose oral and intravaginal tinidazole
    - Metronidazole 2 g daily for 3 days to 5 days
    - High dose intravenous metronidazole
    - 6% Nonoxynol-9 pessaries nightly for 2 weeks and then once weekly for up to 7 months
    - Acetarsol pessaries 2 x 250 mg nocte for 2 weeks
    - Paromomycin sulphate 250 mg pessaries once or twice daily for 2 weeks

  It should be noted that most of these treatments are based on success in one or two patients, each of whom had previously received a wide variety of

treatments. The definition of cure was variable and microbiological follow up was not available in all cases. Additionally, for each case report of cure with specific treatment, there are reports of failure with the same agents.

Pregnancy and breast feeding

- Metronidazole is relatively contraindicated in the first trimester of pregnancy and its safety in pregnancy is not established, although the published data suggest no association with increased teratogenic risk (Evidence Level I) (Burtin et al., 1995; Czeizel & Rockenbauer, 1998; Caro-Paton et al., 1997). In symptomatic disease in early pregnancy local therapies (clotrimazole pessaries 100 mg daily for 7 days or Aci-jel) could be used, but systemic treatment will ultimately be necessary to eradicate the infection.
- The manufacturers recommend that high single dose regimes are avoided during pregnancy and breast feeding.

Management of sexual partners

- Current partners should be screened for the full range of sexually transmitted infections and treated for Trichomonas vaginalis irrespective of the results of investigations.
- In a male contact of Trichomonas vaginalis, found to have non-gonococcal urethritis (NGU) on screening, it is reasonable to treat initially for Trichomonas vaginalis and repeat the urethral smear before treating additionally for non-gonococcal urethritis (Evidence Level III) (Kreiger et al., 1993).

Follow up

Tests of cure should be undertaken if the patient remains symptomatic following treatment, or if symptoms recur.

Trichomonas vaginalis in children (Robinson & Ridgway, 1994)

Trichomonas may be acquired perinatally and occurs in about 5% of babies born to infected mothers. Infection in prepubescent girls is unusual. Infection beyond the first year of life should suggest sexual contact (although other modes of transmission are also postulated) and the child should be appropriately evaluated.

Definitions:

Levels of Evidence:

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- Indicates absence of directly applicable studies of good quality.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is graded and identified for select recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis and effective treatment and management of Trichomonas vaginalis infection

POTENTIAL HARMS

Metronidazole. Patients should be advised not to take alcohol for the duration of treatment and for at least 48 hours afterwards because of the possibility of a disulfiram-like (Antabuse effect) reaction.

CONTRAINDICATIONS

CONTRAINDICATIONS

Metronidazole is relatively contraindicated in the first trimester of pregnancy.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The Clinical Effectiveness Group reminds the reader that guidelines in themselves are of no use unless they are implemented systematically. The following auditable outcome measures are provided:

- All patients found to have Trichomonas vaginalis infection should receive treatment with metronidazole, either as a single dose of 2 g or 400 mg twice daily for at least 5 days.
- Contact tracing should be undertaken and all resulting sexual contacts attending should be treated for Trichomonas vaginalis regardless of the results of their investigations.
- At least 60% of patients should have one or more contacts treated within 1 month.
- 75% of women found to have Trichomonas vaginalis on cervical cytology should have the diagnosis confirmed with a vaginal swab before treatment.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Association for Genitourinary Medicine (AGUM), Medical Society for the Study of Venereal Disease (MSSVD). 2002 national guideline on the management of trichomonas vaginalis. London: Association for Genitourinary Medicine (AGUM), Medical Society for the Study of Venereal Disease (MSSVD); 2002. Various p. [22 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 Aug (revised 2002)

GUIDELINE DEVELOPER(S)

British Association of Sexual Health and HIV - Medical Specialty Society

SOURCE(S) OF FUNDING

Not stated

GUIDELINE COMMITTEE

Clinical Effectiveness Group (CEG)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Author: Jackie Sherrard

Clinical Effectiveness Group (CEG) Members: Keith Radcliffe (Chairman); Imtyaz Ahmed-Jushuf; Jan Welch; Mark FitzGerald; Janet Wilson

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Conflicts of Interest: None

GUIDELINE STATUS

This is the current release of the guideline. This guideline updates a previously released version.

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Available in HTML format from the Association for Genitourinary Medicine (AGUM) Web site. Also available in Portable Document Format (PDF) from the Medical Society for the Study of Venereal Diseases (MSSVD) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- UK national guidelines on sexually transmitted infections and closely related conditions. Introduction. Sex Transm Infect 1999 Aug;75(Suppl 1):S2-3.

Electronic copies: Available in Portable Document Format (PDF) from the Medical Society for the Study of Venereal Diseases (MSSVD) Web site.

The following is also available:

- Revised UK national guidelines on sexually transmitted infections and closely related conditions 2002. Sex Transm Infect 2002;78:81-2

Print copies: For further information, please contact the journal publisher, BMJ Publishing Group.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on June 15, 2000. The information was verified by the guideline developer on October 13, 2000. This summary was updated by ECRI on June 24, 2002.

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